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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

UNITED STATES OF AMERICA, Plaintiff, v. SAMI ANWAR, MID COLUMBIA RESEARCH, LLC, ZAIN RESEARCH, LLC, Defendants.	**4:18-CR-6054-SMJ** INDICTMENT Vio: 18 U.S.C. § 1349 Conspiracy to Commit Wire Fraud (Count 1) 18 U.S.C. § 1349 Conspiracy to Commit Mail Fraud (Count 2) 18 U.S.C. § 1343 Wire Fraud (Counts 3-25) 18 U.S.C. § 1341 Mail Fraud (Counts 26-40) 21 U.S.C. § 843(a)(3) Fraudulently Obtaining Controlled Substances (Counts 41-46)

21 U.S.C. § 843(a)(4)(A)
Furnishing False or
Fraudulent Material
Information
(Count 47)

18 U.S.C. § 981(a)(1)(C),
28 U.S.C. § 2461(c)
Forfeiture Allegations

The Grand Jury charges:

GENERAL ALLEGATIONS

At all times relevant to this Indictment:

Overview of the Conspiracy

1. Beginning at a date unknown, but no later than on or about July 20, 2016, the Defendants, SAMI ANWAR, and his companies, Mid Columbia Research LLC ("MID COLUMBIA RESEARCH"), and Zain Research LLC ("ZAIN RESEARCH"), together with other conspirators both known and unknown to the Grand Jury, devised, perpetrated, and carried out a scheme and artifice designed to enrich themselves financially by falsifying research data for human clinical trials, including a clinical trial for a medical study designed to prevent and lower opioid use and addiction.

2. Defendants' fraudulent scheme included forging and falsifying hundreds of documents to make it appear as though the study was being performed and supervised by a qualified and licensed medical physician; falsifying medical records and data to admit dozens of ineligible subjects into the study, including subjects who were employees of Defendants and family members of Defendants' employees; falsifying research data including, but not limited to: electrocardiograms (ECGs), blood pressure and other vital signs, urinalysis results,

visit and progress notes, and blood specimens drawn from employees of SAMI ANWAR and stolen from unwitting medical patients who were not part of the study; disposing of study medication designated for research subjects by shooting it down the drain, and then falsely recording that it had been injected as required; dangerously hoarding, in attics and desk drawers, opioids intended to be dispensed to study subjects as rescue medication in order to avoid detection, and then falsely recording that they had been dispensed as required; and fabricating diary entries required to be completed by study subjects in order to perpetrate and hide the fraud.

3. In this manner, and as described further herein, Defendants fraudulently sought over a half-million dollars, and fraudulently obtained, at the very least, more than a quarter-million dollars which was designated for legitimate medical research intended to help opioid addicts and to be relied upon as part of the drug approval process regulated by the United States Food and Drug Administration (FDA) before Defendants' fraudulent scheme was uncovered.

FDA and DEA Regulation of Controlled Substances and Clinical Research Trials

4. Drug developers, or "sponsors," perform and oversee clinical research trials or "investigations" to gather data regarding how new drug treatments impact human subjects. Clinical trials are research studies conducted on voluntary human subjects that are designed to answer specific questions about the safety or effectiveness of drugs, vaccines, other therapies, or new ways of using existing treatments.

5. The FDA is responsible for ensuring that drugs intended for human use are safe and effective. FDA relies on the results of clinical trials funded and

conducted by sponsors to make regulatory decisions regarding the approval of drugs.

6. Drug sponsors sometimes contract with contract research organizations (CROs) (sometimes also known as a clinical research organization) in order to oversee and conduct clinical research trials. Per federal regulations (21 C.F.R. § 312.3), a CRO assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor's obligations in carrying out a clinical trial.

7. CROs and Sponsors often contract with multiple research sites to perform clinical trials. Under such an arrangement, each individual research site is responsible for identifying subjects, entering them into the study, performing the study, gathering data, and reporting the data to the Sponsor and/or CRO, all in accordance with protocol and clinical trial agreements entered into among the Sponsor, CRO, and the individual research site.

8. A "principal investigator," "clinical investigator," or "investigator" is the individual responsible for conducting a clinical investigation, including overseeing the selection and qualification of subjects, the dispensation of the study drug, the collection and reporting of data, and the other aspects of the investigation. Under FDA regulations, an investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan (known as a "protocol"), and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; for obtaining the informed consent of each research subject who participates in the investigation; and for ensuring that drugs and controlled substances used in the investigation are appropriately maintained, stored, dispensed, and accounted for.

9. Though the FDA approves drugs for medical use in the United States, the Drug Enforcement Administration (DEA) regulates the handling of all

controlled substances, including those being used by researchers to conduct clinical research. Therefore, a Sponsor, CRO, or research site seeking to conduct an investigation using controlled substances regulated under the Controlled Substances Act must order, possess, store, distribute, and administer the controlled substance pursuant to a valid registration issued by the DEA and applicable regulations. These regulations require, for those drugs designated by the DEA as Schedule I or Schedule II controlled substances, that any such controlled substance be ordered by an approved registrant or registered power of attorney on an official order form signed by the registrant (known as a form DEA-222), that the registrant keep detailed and accurate records for inventory of such substances, and that such substances be stored in locked containers complying with DEA regulations. Moreover, in order to conduct a research study using a Schedule I controlled substance, an entity must seek and obtain approval from the DEA.

The Defendants and Certain Identified Co-Conspirators

10. The Conspiracy involved numerous conspirators, both individuals and entities, known and unknown to the Grand Jury. In addition to the named Defendants, the conspirators included employees of SAMI ANWAR, MID COLUMBIA RESEARCH, ZAIN RESEARCH, other companies owned and controlled by SAMI ANWAR, including a company identified herein as "Company A", and certain of the subjects purportedly participating in the trials. SAMI ANWAR directed all of the acts undertaken in furtherance of the conspiracy.

11. SAMI ANWAR was a resident of the Eastern District of Washington who was the owner, operator, and sole governor of MID COLUMBIA RESEARCH and ZAIN RESEARCH, and the owner, operator, and one of the two governors of Company A. SAMI ANWAR was responsible for all operations of MID COLUMBIA RESEARCH and ZAIN RESEARCH, and also those of

Company A. At no time relevant to this Indictment was SAMI ANWAR ever licensed to practice medicine in the United States.

12. Between at least July 6, 2017 and the present, Defendant Mid Columbia Research LLC ("MID COLUMBIA RESEARCH") was a Washington State for-profit, limited liability corporation and research site with its place of business in Richland, Washington. MID COLUMBIA RESEARCH was owned, operated, and governed by SAMI ANWAR, and held itself out as conducting clinical trials for sponsors and CROs. MID COLUMBIA RESEARCH's employees and operations were controlled and directed by SAMI ANWAR. During the entire course of the Conspiracy, beginning at least on or about July 20, 2016, SAMI ANWAR used MID COLUMBIA RESEARCH's name, and close derivations thereof, on applications to CROs, sponsors, and the Drug Enforcement Administration.

13. At all times relevant to this Indictment, Defendant Zain Research LLC ("ZAIN RESEARCH") was a Washington State for-profit, limited liability corporation and research laboratory with its place of business in Richland, Washington. ZAIN RESEARCH was owned, operated, and governed by SAMI ANWAR. ZAIN RESEARCH held itself out as conducting clinical trials for sponsors and CROs. ZAIN RESEARCH's employees and operations were controlled and directed by SAMI ANWAR.

14. At all times relevant to this Indictment, Company A was a Washington State non-profit corporation and medical facility with its place of business in Richland, Washington. Company A was owned, operated and governed by SAMI ANWAR. SAMI ANWAR's wife was also a governor of Company A at times relevant to the Indictment. Company A, through its healthcare practitioners and staff, held itself out as providing healthcare services to

patients. Company A's employees and operations were controlled and directed by SAMI ANWAR.

15. Company A, ZAIN RESEARCH, and MID COLUMBIA RESEARCH were co-located within the same building, and also shared certain employees and a drug dispensary. Company A provided healthcare services to patients, while ZAIN RESEARCH and, later, MID COLUMBIA RESEARCH, purportedly conducted clinical trials on human subjects on behalf of Sponsors and CROs. Company A employed a licensed physician, known to the Grand Jury and referred to herein by the pseudonym "Dr. Doe." As part of the Conspiracy, because SAMI ANWAR was not a licensed physician, he would falsely represent to sponsors and CROs that Dr. Doe as a licensed physician was the principal investigator for studies of which Dr. Doe had no knowledge and in which Dr. Doe had no participation as required for a ~~principle~~ Principal investigator.

16. ZAIN RESEARCH and MID COLUMBIA RESEARCH generally maintained a "subject binder" for each research subject of each clinical trial. These subject binders included, but were not limited to, documents such as: (1) records documenting the screening or intake process determining whether or not the subject was eligible including, for many studies, medical histories and records reflecting the appropriate diagnoses or conditions; (2) records documenting the subject's informed consent to participating in the study; (3) records documenting the subject's relevant vital signs and other data at the time of admission to the study; (4) records documenting each visit for the subject, including the date and time of the visit and progress notes describing the visit, any concerns or adverse events reported by the subject, and the relevant vital signs and other data at the time of each visit; (5) records documenting the dispensation of the study drug at each visit; (6) records documenting the dispensation of any rescue medication dispensed, that is, any medication provided to the subject to take, as needed,

between visits, and whether any rescue medication was taken or returned by the subject from the prior visit; and (7) subject diaries documenting the subject's subjective experience while on the study, including, as applicable, pain experienced by the subject, the time and date, and whether the subject took rescue medication to relieve any pain experienced.

17. ZAIN RESEARCH and MID COLUMBIA RESEARCH employed various individuals, including: regulatory managers, who were responsible for interacting with Sponsors, CROs, and regulatory agencies; study coordinators, who were responsible for interacting with research subjects in carrying out the study and completing and assembling subject binders; research technicians, who were responsible for conducting blood pressure readings, electrocardiograms (ECGs), drawing blood from subjects, and reporting test results; administrative staff, who were responsible for scheduling subject visits and ensuring that subjects were paid for each visit; drug dispensary staff, who were responsible for ensuring that ZAIN RESEARCH and MID COLUMBIA RESEARCH maintained adequate records demonstrating the dispensation and inventory of each study drug and controlled substance; and others.

18. Company A maintained electronic medical records for each of its patients. Company A employed physicians and other healthcare practitioners, medical assistants, and billing personnel. Other than SAMI ANWAR and certain other high-level management personnel, Company A personnel, including physicians, typically had no involvement regarding the clinical trials being conducted by the Defendants.

The Braeburn Study

19. Braeburn Pharmaceuticals, Inc. (Braeburn), which has its principal place of business in Princeton, New Jersey, is a Sponsor and pharmaceutical company that develops drugs to combat the opioid addiction epidemic. During the

time period relevant to this Indictment, Braeburn sponsored a study for an investigational drug known as CAM 2038. CAM 2038 is an investigational product intended to treat moderate to severe opioid addiction through periodic injections of slow-releasing buprenorphine. During the time period relevant to this Indictment, Braeburn sponsored clinical trials of CAM 2038 in order to gather data for FDA to use in making regulatory decisions regarding CAM 2038 and its potential efficacy and safety in treating opioid use and addiction.

20. Braeburn contracted with Medpace, Inc. (Medpace), a CRO which has its principal place of business in Cincinnati, Ohio, to conduct and provide day-to-day oversight of the CAM 2038 Study. Medpace, in turn, contracted with numerous independent research sites, including MID COLUMBIA RESEARCH, to conduct CAM 2038 studies at individual research site locations.

21. On July 20, 2016, SAMI ANWAR submitted a "Pain Clinical Trial Questionnaire" to Medpace and Braeburn setting forth its intent to participate as an individual research site as part of the CAM 2038 Study. The Questionnaire submitted by SAMI ANWAR falsely stated that it was prepared by a physician employed by Company A, known to the Grand Jury and referred to herein as "Dr. Doe," and that Dr. Doe was the intended clinical investigator. SAMI ANWAR's personal cellular phone number was listed as the "primary phone number," and "Dr." SAMI ANWAR was listed as the primary contact.

22. On or about November 8, 2016, SAMI ANWAR entered into a Clinical Trial Agreement with Medpace, with Braeburn as the intended third-party beneficiary, to perform a study regarding CAM 2038 (referred to herein as "the CAM 2038 Study" or "the Braeburn Study"). While SAMI ANWAR conducted all negotiations with Medpace and Braeburn, SAMI ANWAR is not a licensed physician in the United States, and the clinical investigator on the CAM 2038 study, like other studies, was required to be a licensed physician. Accordingly,

SAMI ANWAR set forth Dr. Doe as the clinical investigator. SAMI ANWAR forged Dr. Doe's signature on the Clinical Trial Agreement between Medpace and "Mid-Columbia Research."

23. Pursuant to the Clinical Trial Agreement, Medpace and Braeburn paid MID COLUMBIA RESEARCH on a per-subject, per-visit basis. That is, MID COLUMBIA RESEARCH was eligible for payment only for subjects who were properly and legitimately enrolled in the study based on the eligibility criteria set forth in the study protocol (hereinafter referred to as "the protocol"), and only for those visits in which the subject actually participated. The Clinical Trial Agreement designated MID COLUMBIA RESEARCH, Attention: SAMI ANWAR, as the payee. As payment agent and CRO, Medpace was responsible to make payment to MID COLUMBIA RESEARCH, using Braeburn funds that Medpace administered on Braeburn's behalf. In order to obtain payment, Defendants, and their known and unknown co-conspirators, submitted study data and per-subject, per-visit information electronically to Medpace, using the interstate wires. Specifically, the Defendants, and their known and unknown conspirators, electronically entered, in Richland Washington, the study data and per-subject, per-visit information into Medpace's electronic data capture (EDC) system, known as ClinTrak and electronically submitted it to Medpace, where it was delivered to, and received by, Medpace on Medpace's servers and electronic systems located in Cincinnati, Ohio. Based on the study data and per-subject, per-visit information entered and submitted by Defendants, Medpace calculated the amounts to be paid to MID COLUMBIA RESEARCH. Medpace then paid MID COLUMBIA RESEARCH, using funds that had been provided by Braeburn for the study, by drawing checks on the Braeburn-provided funds and mailing them, through the United States Postal Service and Federal Express, a private interstate

commercial carrier, to MID COLUMBIA RESEARCH, to SAMI ANWAR's attention.

24. In this manner, and as described further herein, Defendants, through the Conspiracy, obtained $274,642.80, from Braeburn through Medpace, which was deposited into a business banking account controlled by SAMI ANWAR (account number xxxx7574). At times relevant to this Indictment and after receipt of the payments from Braeburn through Medpace, at least $175,000.00 was transferred from that business account into a personal bank account of SAMI ANWAR.

25. In order to gain approval for the study, MID COLUMBIA RESEARCH was also required to submit a completed form FDA-1572, Statement of Investigator, by a licensed and registered physician to act as the clinical investigator for the study. SAMI ANWAR forged Dr. Doe's signature on the FDA-1572 form submitted to Braeburn and Medpace for the Braeburn study. The FDA-1572 form falsely represented to Braeburn and Medpace that the clinical investigator, Dr. Doe, would "personally conduct or supervise" the investigation, would "maintain adequate and accurate records," would comply with FDA regulations and requirements regarding clinical investigator responsibilities, and would conduct the study in accordance with the "relevant, current protocol."

26. In accordance with the Braeburn study protocol and clinical trial agreement, Braeburn provided the "study drug," that is, the CAM 2038 buprenorphine shots that were the subject of the investigation. Buprenorphine is a Schedule III Controlled Substance. MID COLUMBIA RESEARCH was required to purchase and supply the "rescue medication," the morphine and hydrocodone that was dispensed to study subjects to take as needed between visits. Study subjects were required to document any rescue medication that they took between

CAM 2038 shots, and were required to document the time of day, date, and level of pain that the subjects were in at the time of taking any rescue medication.

27. Both types of rescue medication, used in the Braeburn study, morphine and hydrocodone, are Schedule II controlled substances. Hydrocodone is a semi-synthetic opioid synthesized from codeine. It is a narcotic analgesic. Hydrocodone can be combined with acetaminophen, a non-narcotic pain reliever. Morphine is an opioid pain reliever that is naturally occurring in certain plants. Morphine is a narcotic analgesic that can be taken orally or injected intravenously or subcutaneously.

28. Schedule II controlled substances such as morphine and hydrocodone must be ordered through use of a DEA form known as a DEA-222. To obtain a Schedule II controlled substance such as morphine or hydrocodone, the practitioner must not only be a licensed healthcare practitioner, but must be registered with the DEA to provide Schedule II controlled substances. The rescue medication for the Braeburn study was supplied by a company known as Clinical Supplies Management, Inc. (CSM) a clinical supply company with its principal place of business in Fargo, North Dakota. MID COLUMBIA RESEARCH ordered the rescue medication for the Braeburn study by submitting completed and signed DEA-222 forms to CSM in Fargo, North Dakota. CSM then filled the order and mailed the package, via United Parcel Service (UPS), a private interstate commercial carrier, containing the rescue medication to MID COLUMBIA RESEARCH's Richland, Washington facility. SAMI ANWAR used Dr. Doe's DEA registration number and forged Dr. Doe's signature on each of the DEA-222 forms that ordered hydrocodone and morphine for the Braeburn study.

29. Gamma Hydroxybutyrate (GHB) is a central nervous system depressant that is a Schedule I Controlled Substance, the most tightly-controlled type of controlled substance. GHB is commonly known as the "date rape" drug

because it is colorless and odorless and because of its ability to incapacitate victims who ingest it unknowingly and to leave victims with little or no memory afterward. In order to be classified as a Schedule I Controlled Substance, a drug must have no currently accepted medical use in treatment in the United States. In order to perform clinical trials using a Schedule I Controlled Substance such as GHB, an applicant must receive special authorization from the DEA.

30. Flamel Technologies (Flamel) is part of Avadel Pharmaceuticals plc, a pharmaceutical company headquartered in Dublin, Ireland and with its United States headquarters located in Chesterfield, Missouri. In 2016, the FDA permitted Flamel to proceed with a study involving the use of a form of GHB on subjects suffering from narcolepsy, a sleep disorder (the GHB Study). Flamel contracted with INC Research, a CRO located in Raleigh, North Carolina, to conduct the GHB Study.

31. On or about May 12, 2017, MID COLUMBIA RESEARCH submitted an application to DEA to conduct the GHB Study. The application set forth Dr. Doe as the clinical investigator. As with the Clinical Trial Agreement, the FDA-1572 form, and numerous other documents concerning the Braeburn Study, SAMI ANWAR forged Dr. Doe's signature on the DEA application for the GHB Study. Dr. Doe was not aware of the proposed GHB Study at the time of the application's submittal.

COUNT 1
CONSPIRACY TO COMMIT WIRE FRAUD

32. The Grand Jury re-alleges and incorporates by reference paragraphs 1 through 31 of the Indictment as if fully set forth herein. Further, the allegations in all other counts in the Indictment are re-alleged and incorporated into this count as if fully set forth herein.

33. Beginning on a date unknown to the Grand Jury, but no later than on or about July 20, 2016, and continuing until at least on or about January 24, 2018, in the Eastern District of Washington, Defendants SAMI ANWAR, MID COLUMBIA RESEARCH, ZAIN RESEARCH, and other persons and entities both known and unknown to the Grand Jury, did knowingly combine, conspire, and agree to commit certain offenses against the United States including the following offenses, referred to herein as the Conspiracy, to wit, knowingly devised and intended to devise a scheme and artifice to defraud Braeburn, Medpace, and other sponsors, CROs, and prospective sponsors and CROs, both known and unknown to the Grand Jury, and to obtain payments from Braeburn, Medpace, and other sponsors and prospective sponsors, both known and unknown to the Grand Jury, using signals and sounds transmitted by means of wire communication in interstate commerce to execute and attempt to execute the said scheme and artifice to defraud, in violation of 18 U.S.C. §§ 1343, 1349.

34. As part of the Conspiracy described herein, Defendants transmitted, and caused to be transmitted, by means of wire communication in interstate commerce, writings, signals, and sounds, from the Defendants' location in Richland, Washington, to and through the Medpace electronic servers and systems located in Cincinnati, Ohio, in order to advance, further, and carry on the Conspiracy.

WAYS, MANNERS, AND MEANS OF THE CONSPIRACY

Defendants Fraudulently Obtained Approval for the Braeburn Study

35. It was part of the Conspiracy that the Defendants and their known and unknown co-conspirators made numerous false and fraudulent statements and misrepresentations in order to obtain approval to conduct the Braeburn Study, including, for example, the following:

a) Defendants, and other conspirators known and unknown to the Grand Jury, knowingly and intentionally created and submitted to Braeburn and Medpace a false and forged form FDA-1572, Statement of Investigator, bearing Dr. Doe's signature, dated November 9, 2016. Dr. Doe did not personally review or sign the FDA-1572 prior to its submission, nor did he "personally conduct or supervise" the investigation as the form falsely certifies. Defendants never intended Dr. Doe to "personally conduct or supervise" the Braeburn Study, but used his name and credentials in order to make it appear as though a licensed physician was conducting the study so that Braeburn and Medpace would approve it. As Defendants knew, Braeburn and Medpace would not have approved MID COLUMBIA RESEARCH's participation without a licensed physician's certification, on an FDA-1572, that he would personally conduct or supervise the investigation.

b) Defendants also knowingly and intentionally created and submitted to Braeburn and Medpace a false and forged Clinical Trial Agreement, bearing Dr. Doe's purported signature, dated November 8, 2016. Dr. Doe did not review or sign the Clinical Trial Agreement prior to Defendants submitting it. The Clinical Trial Agreement falsely represented to Medpace and Braeburn that the study would "be conducted under the direction of [Dr. Doe], and that [Dr. Doe] shall be responsible for the oversight and direction of the study." The Clinical Trial Agreement also falsely represented that Dr. Doe and MID COLUMBIA RESEARCH would comply with all FDA rules and regulations, and would perform the study in compliance with the protocol. As Defendants knew, Braeburn and Medpace would not have approved MID COLUMBIA RESEARCH's participation without a Clinical Trial Agreement with a licensed physician stating that he would be responsible for the oversight and direction of the study, and that

he would ensure that the study be performed pursuant to applicable regulations and the protocol.

Defendants' Fraudulently Enrolled Ineligible Subjects into the Braeburn Study

36. As part of the Braeburn Study, the Defendants, and other conspirators both known and unknown to the Grand Jury, enrolled a total of forty (40) subjects into the Braeburn Study who were all purportedly eligible to be subjects under the terms and conditions of the Clinical Trial Agreement and the protocol. In fact, as the Defendants knew, none of the subjects enrolled in the Braeburn Study were eligible under the terms of the protocol or the Clinical Trial Agreement. Nonetheless, it was part of the Conspiracy that the Defendants, and other known and unknown conspirators, sought and received hundreds of thousands of dollars in payments from Braeburn and Medpace for the purported visits of the ineligible subjects.

37. It was part of the Conspiracy that the Defendants, and other known and unknown conspirators, enrolled dozens of subjects into the Braeburn Study who the Defendants knew, at the time of their enrollment, were ineligible under the terms of the Clinical Trial Agreement and the protocol. The Defendants did this with the specific intent of fraudulently obtaining the per-visit, per-subject payments from Braeburn and Medpace corresponding to the ineligible subjects, which ranged up to $1,800.00 per visit under the terms of the Clinical Trial Agreement, and totaled well over a quarter-million dollars in fraudulently obtained payments from Braeburn and Medpace before the Conspiracy was uncovered and stopped.

38. As the Defendants knew, the Clinical Trial Agreement made compliance with the protocol an explicit condition of the per-visit, per-subject payments. The protocol included specified inclusion criteria that any individual proposed as a subject for the Braeburn Study was required to meet in order to be

eligible to be enrolled in the Braeburn Study. The protocol also included specified exclusion criteria, any one of which would make an otherwise qualifying proposed subject for the Braeburn Study ineligible.

39. For any clinical trial, compliance with the inclusion and exclusion criteria in enrolling subjects, as determined and verified by the clinical investigator, is essential for any of the results of the trial to be of value to the sponsor. Accordingly, Braeburn and Medpace provided the Defendants with standardized screening visit checklists that were required to be filled out per the protocol and reviewed by the clinical investigator, Dr. Doe, and signed and dated by him, affirmatively representing whether the proposed subject met all of the inclusion criteria and did not fall under any of the exclusion criteria.

40. In violation of the Clinical Trial Agreement and protocol, none of the 40 subjects in the Braeburn Study for which Defendants sought and received payment were seen, admitted, or had their medical condition or any of the inclusion or exclusion criteria assessed by Dr. Doe in determining their eligibility to participate in the study, making each and every subject ineligible to participate in the study. If Braeburn and Medpace had known that Dr. Doe had not seen or admitted any of the subjects, and had not assessed any of their medical conditions or inclusion or exclusion criteria or determined them eligible for the study, Braeburn and Medpace would not have authorized payment for any of the subjects.

41. Additionally, despite knowing of the inclusion and exclusion criteria of the protocol, the Defendants, and other conspirators both known and unknown to the Grand Jury, enrolled dozens of individuals as subjects in the Braeburn Study that did not meet the inclusion criteria and met at least one of the exclusion criteria at the time of their initial screening. Nonetheless, the Defendants, and other conspirators both known and unknown to the Grand Jury, knowingly and intentionally submitted false and misleading information to Braeburn and Medpace

to make it appear that these ineligible subjects were eligible. In this manner, the Defendants were able to defraud Braeburn and Medpace of hundreds of thousands of dollars in per-visit, per-subject payments for ineligible subjects.

42. The protocols' inclusion criteria included, but were not limited to, a requirement that the proposed subject had been treated with daily opioids for moderate to severe chronic lower back pain for a minimum of three (3) months (the Braeburn Study Protocol was amended in August of 2017 to clarify that certain new subjects with a documented history and diagnosis of chronic pain (not just lower back pain) were eligible). This inclusion criteria was essential to the efficacy of the Braeburn Study, which was attempting to evaluate the efficacy and safety of using injections of CAM2038 on subjects with a recent history of moderate to severe chronic pain currently being treated with opioids. If a person in fact had not been suffering from moderate to severe chronic pain for at least three (3) months, then enrolling that person as a subject in the Braeburn Study would not in any way advance any understanding of the safety or efficacy of injections of CAM2038 for suffers of moderate to severe chronic pain. Similarly, if a person in fact had not been treating their moderate to severe chronic pain for at least three (3) months with daily opioids, then enrolling that person as a subject in the Braeburn Study would not in any way advance any understanding of the safety or efficacy of injections of CAM2038 as an alternative for suffers of moderate to severe chronic pain. Further, in each instance, inclusion of such an ineligible subject would corrupt the results of the Braeburn Study.

43. Despite knowing of this inclusion criteria and its essential role in the efficacy of the Braeburn Study, the Defendants, and other conspirators, both known and unknown to the Grand Jury, caused ineligible persons to be enrolled as subjects in the Braeburn Study who, as the Defendants knew, had not been suffering from moderate to severe chronic pain for at least three (3) months and/or

were not being treated with opioids at all. If Braeburn or Medpace had been aware that subjects who did not meet this inclusion criteria were nonetheless being enrolled in the study they would not have paid the Defendants for any of the per-visit amounts corresponding to that subject.

44. The Braeburn Study inclusion criteria also included, but was not limited to, a requirement that all subjects be provided written informed consent prior to the conduct of any study-related procedures. In addition to being a cornerstone of modern medical research, the informed consent of a subject to conduct medical tests on that subject is needed in order for the results of that test to be usable and of any value, as well as to ensure that the subject is willingly participating in the study. Accordingly, the protocol required that all subjects sign approved informed consent forms, any revised informed consent forms, and that the date and time of the subject's signature on the informed consent form be documented along with study personnel who conducted the informed consent process.

45. Despite knowing of this inclusion criteria and its essential role in the efficacy of the Braeburn Study, the Defendants, and other conspirators both known and unknown to the Grand Jury, knowingly falsified documentation submitted to Braeburn and Medpace in order to falsely represent that these subjects had provided informed consent when in fact they had not, either because the subject was never provided nor signed an informed consent form or because, contrary to the protocol, the nature of the study and its risks and benefits were not explained to the subject. When Braeburn and Medpace later became aware of the false representations related to the lack of informed consent of multiple subjects, as well as other false representations, they terminated MID COLUMBIA RESEARCH's participation in the Braeburn Study.

46. The Braeburn Study exclusion criteria included, but were not limited to, excluding as a subject any person who was an employee of the research site or an employee's family member. The protocol also required that the study be conducted ethically and consistent with good clinical practice, which would, among other things, prohibit enrolling as subjects employees of entities co-located with the research site that were also co-owned and co-operated by the same individual owner and operator of the research site, or the family members of such employees. The exclusion criteria and requirements of the protocol were essential to the integrity and efficacy of the Braeburn Study as they prevented the conflicts of interest inherent when employees of a research site or its owner and operator, or their family members, are enrolled as subjects in a clinical trial. Using employees or family members as subjects corrupts the results of any clinical trial and renders its findings, certainly as to those subjects, useless. Pursuant to the Clinical Trial Agreement and the protocol, any employee of MID COLUMBIA RESEARCH, ZAIN RESEARCH, or Company A, or any family member of any employee, was ineligible to participate as a subject, and MID COLUMBIA RESEARCH was not eligible to receive payment from Braeburn and Medpace for any such subject.

47. If Braeburn and Medpace had been aware that subjects who were employees of Defendants or of Company A, or a family member of any employee, were nonetheless being enrolled in the study, they would not have paid the Defendants for any of the per-visit amounts corresponding to any of those subjects.

48. Only by way of example of the Conspiracy's fraudulent enrollment of ineligible subjects, the Defendants, and other conspirators, both known and unknown to the Grand Jury, knowingly and intentionally caused standard screening visit checklists and other eligibility and enrollment documentation for multiple subjects of the Braeburn Study, including but not limited to, Subject 068-017; Subject 068-027; Subject 068-028; Subject 068-034; Subject 068-035; and Subject

068-039, to be submitted to Braeburn and Medpace falsely representing that these subjects were eligible for enrollment as subjects in the Braeburn Study. Specifically, for example, the Defendants, and other conspirators, both known and unknown to the Grand Jury, falsely represented that the inclusion criteria of being treated with daily opioids for a minimum of three months prior to screening had been met, when, as the Defendants knew, Subject 068-017; Subject 068-027; Subject 068-028; Subject 068-034; Subject 068-035; and Subject 068-039 were not being treated with daily opioids at all.

49. For Subject 068-017; Subject 068-027; Subject 068-028; Subject 068-034; Subject 068-035; and Subject 068-039, the Defendants, and other conspirators, both known and unknown to the Grand Jury, caused a signature, purporting to be Dr. Doe's signature as the Investigator, without Dr. Doe's knowledge or consent, to be forged on the standard screening visit checklists and other enrollment and eligibility documentation for each of those subjects all bearing dates between May 29, 2017, and September 20, 2017, affirmatively and falsely attesting that these subjects met all of the inclusion criteria of the Braeburn Study. As the Defendants knew, Dr. Doe did not screen any of the 40 subjects, including, for example, Subject 068-017; Subject 068-027; Subject 068-028; Subject 068-034; Subject 068-035; or Subject 068-039, as part of the Braeburn Study, did not determine their eligibility to participate in the Braeburn Study, and had no part in filling out or signing any of the corresponding standard screening checklists or other eligibility and enrollment documentation submitted to Braeburn and Medpace.

50. Based in part on the false screening visit checklists and other eligibility and enrollment documentation submitted to Braeburn and Medpace for Subject 068-017; Subject 068-027; Subject 068-028; Subject 068-034; Subject 068-035; and Subject 068-039, the Defendants sought over $50,000.00 from

Braeburn and Medpace in payments directly tied to those ineligible subjects for which Defendants, and their known and unknown co-conspirators, falsely claimed eligibility.

51. Only by way of further example of the Conspiracy's fraudulent enrollment of ineligible subjects, the Defendants, and other conspirators, both known and unknown to the Grand Jury, knowingly and intentionally caused a standard screening visit checklist and other eligibility and enrollment documentation for Subject 068-011 to be submitted to Braeburn and Medpace falsely representing that this subject had a clinical diagnosis of moderate to severe chronic pain that had been treated with daily opioids for three months or more. In fact, as the Defendants knew, Subject 068-011 had no such clinical diagnosis and the medical records held by the Defendants reflected that on April 12, 2017, the date of the falsified standard screening visit checklist, the subject was "present for lower back pain" with "no historical diagnoses." Based in part on the false screening visit checklists and other falsified materials submitted to Braeburn and Medpace for Subject 068-011, the Defendants claimed $14,325.00 from Braeburn and Medpace in payments directly tied to this ineligible subject. When Braeburn and Medpace later became aware of the false representations related to the eligibility of Subject 068-011, as well as other false representations, through a for-cause audit performed by Braeburn and Medpace personnel at the location of the Defendants' business in October 2018 (hereinafter the "October Audit"), they terminated MID COLUMBIA RESEARCH's participation in the Braeburn Study.

52. Only by way of further example of the Conspiracy's fraudulent enrollment of ineligible subjects, the Defendants, and other conspirators, both known and unknown to the Grand Jury, intentionally and fraudulently enrolled Subject 068-022 and Subject 068-027 in the Braeburn Study knowing that Subject 068-022 and Subject 068-027 were family members of an employee of MID

COLUMBIA RESEARCH and SAMI ANWAR. Specifically, the Defendants knew that Subject 068-022 was the father of the lead MID COLUMBIA RESEARCH study coordinator for the Braeburn Study and Subject 068-027 was a cousin of that same study coordinator. Both Subject 068-022 and Subject 068-027 were therefore ineligible to participate in the Braeburn Study. Based in part on the false representations regarding the eligibility of Subject 068-022 and Subject 068-027, the Defendants sought a total of $22,800 from Braeburn in payments directly tied to those ineligible subjects. If Braeburn and Medpace had been aware that Subject 068-022 or Subject 068-027 were ineligible family members of MID COLUMBIA RESEARCH's lead study coordinator, they would not have paid the Defendants for any of the respective per-visit amounts corresponding to those subjects, nor would they have permitted either to participate in the study.

53. It was also part of the Conspiracy to falsify medical records of persons who were ineligible as subjects for the Braeburn Study to make it appear that these persons had the appropriate diagnosis and opioid use and therefore eligible for enrollment, and included these false records as part of the fraudulent eligibility and enrollment documentation submitted to Braeburn and Medpace. The Defendants did this with the specific intent to deceive Braeburn and Medpace and to collect per-visit payments for ineligible subjects.

54. By way of example only, the Defendants, and other conspirators both known and unknown to the Grand Jury, submitted, in or about July 2017, falsified medical records and other eligibility and enrollment documentation to Braeburn and Medpace for Subject 068-030, an employee of SAMI ANWAR and Company A, falsely representing that that subject suffered from moderate to severe chronic pain, and also representing that she had no history of asthma. In November 2017, the Defendants, and other conspirators both known and unknown to the Grand Jury, submitted false medical records purportedly from Company A for Subject

068-030 to a different clinical study, regarding asthma, that purportedly indicated that Subject 068-030 suffered from asthma and had no history of any chronic pain. These Company A medical records contained a forged signature of Dr. Doe, who was completely unaware of the asthma study and did not review any medical records for it nor play any role in it. Nonetheless the Defendants claimed a total of $10,725.00 from Braeburn and Medpace for the per-visit payments for Subject 068-030. If Braeburn and Medpace had been aware that the Defendants, and other conspirators both known and unknown to the Grand Jury, falsified medical records to justify the eligibility of subjects, they would not have paid the Defendants for any of the costs or per-visit amounts corresponding to that subject and would have terminated MID COLUMBIA RESEARCH's participation in the study.

Defendants Fraudulently Obtained Per-Visit Payments from Braeburn

55. It was part of the Conspiracy, for the Defendants, and other conspirators, both known and unknown to the Grand Jury, to fraudulently seek and obtain per-visit payments for subjects of the Braeburn Study not only for subjects who were never eligible to participate in the trial to begin with, but also for visits that were not completed as required by the Clinical Trial Agreement and the protocol. In this manner, the Defendants received hundreds of thousands of dollars in payments from Braeburn and Medpace for falsified subject visits that never took place.

56. Under the Clinical Trial Agreement and the protocol, in addition to securing per-visit subject payments, the weekly subject visits, if properly and actually conducted, could cause a subject to become ineligible to continue to participate in the study, for example, because of abnormal test results or the amount of pain reported by the subject. In addition, a subject not showing up for weekly visits would likely cause the subject to become ineligible to continue to participate. In the event that a subject was discontinued from the study, as the

Defendants knew, they could not continue to claim per-visit subject payments for that subject. Accordingly, it was part of the Conspiracy to falsify the documentation of subjects' weekly visits and submit false documentation to Braeburn and Medpace for each weekly visit, to create the appearance that the subjects had been present for their weekly visits, that the weekly visits had been properly conducted per the protocol, and that none of the criteria in the protocol that would render the subject ineligible to continue had been triggered.

57. Per the terms of the Clinical Trial Agreement compliance with the different weekly visit requirements in the protocol was a necessary condition of the per-visit subject payments from Braeburn and Medpace. The protocol required enrolled subjects to visit the business location of the Defendants each week during the study. The protocol provided for the specific required steps that had to be accomplished at these different weekly visits, including the administration of the CAM 2038 shot as well as the dispensing of rescue medication. By way of example only, some weekly visits required obtaining clinical laboratory assessments through blood draws and laboratory testing, while other weekly visits required urine tests for drug screening, and still other weekly visits required electrocardiograms (ECGs) to be conducted on the subjects. Further, all of the weekly visits required obtaining the vital signs of the subjects and all of the weekly visits required written progress notes documenting aspects of the weekly visit, including any adverse events reported by the subjects. For their weekly participation subjects were entitled, under the protocol, to payment of $75 per visit.

58. The protocol required that the Investigator conduct the weekly visits or, to the extent any activities were delegated, to have direct oversight of all delegated activities and to document any delegation of responsibilities. In fact, as the Defendants knew, Dr. Doe, as the Investigator, did not conduct any of the weekly visits, did not delegate any activities to others, and did not have direct

oversight, or any oversight, of the activities of any of the Defendants, and/or other conspirators both known and unknown to the Grand Jury, related to subject weekly visits. Many of the purported weekly visits did not take place at all, while many other subjects attended visits only to receive their weekly check for participating in the study, and received neither the CAM 2038 study drug, nor the rescue medication.

59. By way of example only, the protocol required that the Investigator, or his medically qualified delegate, take and record subject vital signs such as temperature, blood pressure, pulse rate, pulse oximetry, and respiratory rate, at each weekly subject visit. However, subjects often did not attend their weekly visits and accordingly the Defendants, and other conspirators both known and unknown to the Grand Jury, routinely falsified documentation showing that subjects' vital signs had been taken, validly recorded, and, as indicated by the forged signature of Dr. Doe, reviewed by the Investigator to assess the results for any clinical significance. If Braeburn and Medpace had been aware that any of the weekly vital signs were being falsely or fraudulently represented, they would not have paid the Defendants for the corresponding subject and the corresponding weekly visit and would have terminated MID COLUMBIA RESEARCH's participation in the study.

60. By way of further example only, the protocol required that each subject be seen by the Investigator or his medically qualified delegate at each weekly visit and that the Investigator document the notes of the visit, including any adverse events reported by the subject or observed by the Investigator. However, as subjects often did not attend their weekly visits, the Defendants, and other conspirators both known and unknown, routinely created fraudulent progress notes falsely stating that the subject had visited, and falsely recording events, including but not limited to, the dispensing of rescue medication to the subject, statements

that a subject purportedly made or did not make, whether the subject received an injection, and whether certain required assessments had been performed.

61. These false and fraudulent progress notes often contained the forged signature of Dr. Doe, as the Investigator, falsely indicating that he had reviewed the progress notes for any clinically significant events when, as the Defendants, and other conspirators both known and unknown to the Grand Jury, knew, Dr. Doe had no knowledge that his signature was being forged, had not reviewed the progress note nor seen the subject or any of the subject documentation for the visit, and had not had any involvement with the purported weekly visit of the subject. If Braeburn and Medpace had been aware of any one of these false and fraudulent progress notes for visits that did not take place, or forged signatures of Dr. Doe on the purported progress notes, they would not have paid the Defendants for the corresponding weekly visit for that subject and would have terminated the study.

62. By way of further example only, the protocol required that ECGs be performed on subjects on certain specified weekly visits. The protocol specified when the ECGs needed to be performed in relation to, for instance, injections of CAM2038. The protocol further required that the Investigator, or other medically-qualified individuals that he may delegate, review all ECGs to ascertain the subject's heart activity, including whether the subject was experiencing any abnormalities and whether any such abnormalities were clinically significant, presented any health or safety concerns, and whether referral to a cardiologist was necessary.

63. It was part of the Conspiracy to falsify ECGs by performing them on employees of MID COLUMBIA RESEARCH and SAMI ANWAR, who were not subjects in the Braeburn Study, and then fraudulently submitting the results to Braeburn and Medpace, falsely representing them to be those of various subjects. Specifically, the Defendants, and other conspirators both known and unknown to

the Grand Jury, would routinely falsify the date and time of the ECGs and forge Dr. Doe's signature or initials to make it appear that the ECGs had been conducted and reviewed as required by the protocol when in fact they had not. When Braeburn and Medpace later became aware of the false representations related to purported subject ECGs, as well as other false representations, through the October Audit, they terminated MID COLUMBIA RESEARCH's participation in the Braeburn Study. Had Braeburn/Medpace been aware of any one of these false and fraudulent ECGs they would not have paid the Defendants for the corresponding weekly visit for that subject.

64. By way of further example only, the protocol required that on certain specified weeks during the Braeburn Study a 12-panel urine drug screen would be administered to test for the presence of certain drugs of abuse including but not limited to cocaine, methamphetamines, and barbiturates. The protocol required that the results of these subject urine drug screen tests be provided to Braeburn and Medpace as part of ensuring continued subject eligibility and for data collection purposes. However, because subjects often did not attend their weekly visits and did not receive the rescue medication, meaning they would not test positive for the opioids that Defendants falsely claimed they were taking, the Defendants, and other conspirators both known and unknown, would sometimes use the urine samples of some patients of Company A, who the Defendants knew would (unlike the subjects) test positive for opioids. Defendants, and their known and unknown co-conspirators, would then provide the resulting false and fraudulent urine samples to Braeburn and Medpace's laboratory as though they had come from subjects. Had Braeburn and Medpace been aware of any one of these false and fraudulent urine drug screening tests, they would not have paid the Defendants for the corresponding weekly visit of that subject and would have terminated MID COLUMBIA RESEARCH's participation in the study.

65. By way of further example only, the protocol required that on certain specified weeks during the Braeburn Study that the Investigator, or his medically-qualified delegate, take blood samples from the subjects to be tested for non-drug related items such as red blood cell count, mean corpuscular volume, mean corpuscular hemoglobin concentration, and platelets. The protocol required that the blood samples be submitted to Medpace's laboratory for testing and that the Investigator review and sign all laboratory reports in order to document the data collection for the study, the appropriate safety monitoring of subjects, and any clinically significant items or other abnormalities.

66. Because subjects frequently did not attend their weekly visits, the Defendants, and other conspirators both known and unknown to the Grand Jury, directed and participated in the collection of blood samples from persons other than subjects in order to submit blood samples to a central laboratory as required by the protocol. SAMI ANWAR designated one MID COLUMBIA RESEARCH study coordinator to provide fraudulent blood samples, and directed other employees of SAMI ANWAR and MID COLUMBIA RESEARCH to draw that study coordinator's blood and to falsely label it as being from subjects who did not attend their weekly visit, and then to submit the samples to the laboratory for testing.

67. At times the Defendants, and other conspirators both known and unknown and to the Grand Jury, directed and participated in stealing blood samples taken from patients of Company A who had no knowledge of, and did not consent to, the use of their blood samples in the Conspiracy. At SAMI ANWAR's direction, at times Company A employees would tell Company A patients that they qualified for a free laboratory blood test, draw the patients' blood, falsely label the blood as being from the Braeburn Study subject who had not attended the weekly visit, and then submit the fraudulent blood sample for testing.

68. Whether stolen from patients or taken from employees of SAMI ANWAR, the Defendants, and other conspirators both known and unknown to the Grand Jury, knowingly and intentionally used the laboratory results of the stolen and otherwise ill-gotten blood samples to make it appear that they were complying with the protocol in order for the Defendants to fraudulently obtain the corresponding per-visit payments from Braeburn and Medpace, which were typically worth hundreds of dollars more than the subject weekly visits that did not require blood testing. Moreover, a failure to submit blood laboratory results as required by the protocol for any one subject would have precluded receiving any further payment from Braeburn and Medpace for that subject.

69. Moreover, if Braeburn and Medpace had been aware of the Defendants' theft and use of stolen blood, they would not have paid the Defendants for the corresponding weekly visit for those subjects, and would have terminated MID COLUMBIA RESEARCH's participation in the study.

Defendants Fraudulently Obtained Controlled Substances and Misrepresented Their Dispensation of Controlled Substances

70. As part of the Conspiracy, Defendants, and their known and unknown co-conspirators, fraudulently obtained and fraudulently misrepresented their dispensation of the controlled substances that were part of the Braeburn Study, including, for example, the following:

71. Defendants' orders of the morphine rescue medication and the hydrocodone rescue medication were fraudulent. Morphine and hydrocodone are Schedule II controlled substances. As such, these medications can only be ordered for legitimate medical or research purposes by an authorized registrant with a registration for Schedule II controlled substances, and only on a DEA-222 form signed by an authorized signator of the registrant. In the case of the Braeburn

Study, Dr. Doe was the registrant, and was the only person authorized by DEA to sign a DEA-222 form. The DEA-222 forms used by Defendants to obtain the hydrocodone and morphine that was purportedly for the Braeburn study, however, were not signed by Dr. Doe. Instead, SAMI ANWAR forged Dr. Doe's signature, and Defendants knowingly submitted the forged DEA-222 using Dr. Doe's DEA registration number and forged signature. Moreover, Defendants did not order the hydrocodone or morphine for legitimate use in the Braeburn Study, but instead as part of the Conspiracy, to make it look as though the study was being conducted legitimately and pursuant to the protocol, and so Defendants could fraudulently bill and obtain payment from Braeburn and Medpace for the study.

72. Defendants knowingly and intentionally ordered, obtained, and dispensed the CAM 2038 buprenorphine shot, the morphine rescue medication, and the hydrocodone rescue medication for study subjects who were not eligible to participate in the study, including, but not limited to, the specific ineligible subjects discussed above. Defendants ordered the CAM 2038 buprenorphine, the morphine, and the hydrocodone to make it appear as though the study subjects were legitimate study participants, and so Defendants could fraudulently bill and obtain payment from Braeburn and Medpace for these ineligible participants.

73. Defendants knowingly and intentionally ordered, obtained, and removed from the Defendants' drug dispensary the CAM 2038 buprenorphine shot, the morphine rescue medication, and the hydrocodone rescue medication for purported study subjects who were not actually participating in the study or attending their weekly visits. Defendants ordered the buprenorphine, the morphine, and the hydrocodone to make it appear as though the purported study subjects were participating in the study when in fact they were not, and so Defendants could fraudulently bill and obtain payment from Braeburn and

Medpace for these supposed participants who were, in fact, not participating in the study.

74. Although Defendants removed the CAM 2038 buprenorphine shot from the Defendants' drug dispensary, because most of the purported study participants were, in fact, neither eligible for nor actually participating in, the study, and therefore did not come in for their study visits as the protocol required, the CAM 2038 buprenorphine study drug was frequently not provided to the study subjects. Instead, SAMI ANWAR directed his employees to shoot the CAM 2038 buprenorphine shots down the drain, so that the syringe containing the CAM 2038 buprenorphine shot for that particular research subject, for that particular visit, would be empty and it would appear as though the CAM 2038 buprenorphine shot had been provided to the study subject as the protocol required. At SAMI ANWAR's direction, the empty syringes were then collected and provided to Medpace and Braeburn in their monitoring visits, to make it appear as though the study was being conducted pursuant to the protocol. SAMI ANWAR also directed that MID COLUMBIA RESEARCH employees complete false documentation in the subject study binder falsely reflecting that the CAM 2038 buprenorphine study drug had been provided to the subject as the protocol required.

75. SAMI ANWAR further directed his employees, including employees of MID COLUMBIA RESEARCH, to submit falsified electronic entries into Medpace's Interactive Response Technology (IRT), a web-based computer interface between MID COLUMBIA RESEARCH and Medpace used to track MID COLUMBIA RESEARCH's dispensation of both rescue medications and the CAM 2038 syringes. All IRT submissions to Medpace from the Defendants traveled in interstate wires through the Medpace servers located in Cincinnati, Ohio.

76. SAMI ANWAR directed the creation of false subject binder documentation and the submission of false IRT data to Medpace in order to make it appear to Medpace and Braeburn that the CAM 2038 syringes were being dispensed for subjects when in fact they were not. This allowed MID COLUMBIA RESEARCH to falsely bill Medpace and Braeburn for the visit, and to continue billing Medpace and Braeburn for that purported study subject for future visits.

77. Similarly, although Defendants removed the morphine rescue medication and the hydrocodone rescue medication from the Defendants' drug dispensary, because most of the purported study participants were, in fact, neither eligible for nor actually participating in, the study, and therefore did not come in for their study visits as the protocol required, the rescue medication was frequently not provided to the study subjects. Instead, SAMI ANWAR directed that MID COLUMBIA RESEARCH employees put the removed rescue medication into plastic bags labeled "No-Show" and hid the bags in a box labeled "B-Study" in the attic of the Defendants' business location, along with empty pill bottles that Defendants falsely stated had been provided to subjects. SAMI ANWAR further directed his employees, including employees of MID COLUMBIA RESEARCH, to falsify entries into the Medpace IRT to make it appear to Medpace and Braeburn that rescue medications were being dispensed to subjects when in fact they were not. SAMI ANWAR directed these actions to make it appear as though the study was being conducted and the rescue medication being dispensed pursuant to the protocol, and so that the amount of rescue medication in the Defendants' drug dispensary would match the amount that Defendants falsely represented had been provided to subjects. SAMI ANWAR also directed his employees, including employees of MID COLUMBIA RESEARCH, to complete false documentation in the subject study binder falsely reflecting that the rescue medication had been

provided to the subject as the protocol required. SAMI ANWAR directed these actions be performed so that Defendants could bill Medpace and Braeburn for the visit, and continue billing Medpace and Braeburn for that purported study subject for future visits.

Defendants Fraudulently Concealed Their Scheme

78. As part of the Conspiracy, Defendants, and their known and unknown co-conspirators, not only knowingly and intentionally concealed the truth from Braeburn and Medpace, but made numerous misrepresentations and false statements in order to prevent Medpace and Braeburn from discovering the Conspiracy.

79. Throughout the Braeburn Study, as part of the Conspiracy, SAMI ANWAR would fraudulently pose as Dr. Doe, without his knowledge or consent, on the phone in conversations with Medpace and Braeburn when a representative from Medpace or Braeburn called MID COLUMBIA RESEARCH or wanted to speak to Dr. Doe. SAMI ANWAR did this in order to prevent detection of the Conspiracy; Defendants knew that Dr. Doe was not conducting or supervising the Braeburn Study and was not knowledgeable about the Braeburn Study or any of the subjects, and that if Medpace or Braeburn were to contact Dr. Doe, they would discover the Conspiracy.

80. In December 2016, Medpace and Braeburn requested from MID COLUMBIA RESEARCH the mobile phone number for Dr. Doe, whom they believed to be the Investigator, in case Medpace or Braeburn needed to discuss the study with Dr. Doe after hours or when he was out of the office, including in the event of an emergency. Defendants knew that Dr. Doe was not conducting or supervising the Braeburn Study and was not knowledgeable about the Braeburn Study, and that if Medpace or Braeburn contacted Dr. Doe, they would discover the Conspiracy. Therefore, in order to prevent Braeburn and Medpace from

uncovering the Conspiracy, at SAMI ANWAR's direction, MID COLUMBIA RESEARCH instead provided the number for one of SAMI ANWAR's cellular phones.

81. In September 2017, a routine monitoring visit by Medpace revealed certain inconsistencies in subject binder and other study documentation. In addition, in September of 2017, Medpace received an anonymous call from an employee of MID COLUMBIA RESEARCH who advised that, among other things, subject diaries were being forged, subject medical records were being falsified, and rescue medications and CAM 2038 shots were not actually being dispensed as represented. Based on the inconsistencies and the employee's allegations, Medpace and Braeburn announced to MID COLUMBIA RESEARCH that they would be conducting a for-cause audit on October 11 and 12, 2017 (the October Audit). Medpace and Braeburn explained that the audit would involve the review of documentation related to research subjects, data verification, and drug dispensation and administration. In response to the upcoming audit, SAMI ANWAR directed that MID COLUMBIA RESEARCH perform a reconciliation comparing the number of pills of morphine and hydrocodone that its records falsely reflected had been provided to research subjects as rescue medication with the number of pills that the Defendants' drug dispensary had actually removed and place in the "No Show" bags. SAMI ANWAR directed this reconciliation because he knew that Medpace and Braeburn's audit would be verifying that all of the rescue medication that MID COLUMBIA RESEARCH's subject binders had reflected as being provided to subjects had actually been removed from the drug dispensary. The reconciliation performed by MID COLUMBIA RESEARCH revealed that approximately 590 hydrocodone pills that MID COLUMBIA RESEARCH's records falsely reflected were provided to research subjects were still in the drug dispensary shared by Company A, and ZAIN RESEARCH and

MID COLUMBIA RESEARCH. SAMI ANWAR therefore directed that these pills be removed from the drug dispensary to conceal the Conspiracy from the Medpace and Braeburn auditors. Defendants, and their known and unknown conspirators, then placed the pills in a sealable reusable plastic baggie, and placed the baggie in SAMI ANWAR's desk drawer in his office so that it would appear to Braeburn and Medpace that all of the rescue medication had been provided to research subjects as MID COLUMBIA RESEARCH's subject binders falsely reflected. In January of 2018, pursuant to the execution of a search warrant, the DEA found a sealable reusable plastic baggie in SAMI ANWAR's desk drawer in his office containing 590 hydrocodone pills.

82. Defendants knew that Braeburn and Medpace would also be reviewing subject binders to ensure that the Braeburn Study was being conducted pursuant to the protocol and that each of the subjects for which MID COLUMBIA RESEARCH was billing Braeburn and Medpace were making weekly visits, having vital signs and other study data drawn, receiving the study drug, and receiving rescue medication. Because the vast majority of the study subjects were not, in fact, actually participating in the study, SAMI ANWAR directed that MID COLUMBIA RESEARCH employees falsify this information in preparation for the October Audit. At SAMI ANWAR's direction, MID COLUMBIA RESEARCH employees falsified subject study attendance for their visits, vital sign data, study drug injections, receipt of the rescue medication, progress notes from the study participant, including purported pain levels and experience on the study, and study results. At SAMI ANWAR's direction, when MID COLUMBIA RESEARCH employees had "completed" the binder by falsifying the necessary information, they placed the binder in SAMI ANWAR's office for him to review the documentation and forge Dr. Doe's signature to make it appear as though the

information had been reviewed by the Investigator. Once SAMI ANWAR had done so, the binder was ready for review by Braeburn and Medpace.

83. Defendants' efforts to falsify these subject binders in advance of the audit were unsuccessful. The October Audit documented that: (1) subject signatures on revised consent forms appeared to be falsified; (2) the subject binders did not contain sufficient medical documentation to support subject eligibility based on daily opioid use or a history of chronic pain; (3) MID COLUMBIA RESEARCH had altered documentation without basis to make the subjects appear eligible; (4) the abnormalities documented in the majority of the ECGs were not adequately evaluated; (5) ECG results appear to have been doctored or falsified; (6) progress notes were not accurate, and appeared to have been done from a template; and (7) adverse events were not accurately or adequately reported, with almost no adverse events listed for the subjects. Ultimately, the auditors considered many of these findings critical and recommended that all data from MID COLUMBIA RESEARCH be thrown out and that MID COLUMBIA RESEARCH's participation be terminated, which Braeburn and Medpace did on October 23, 2017.

84. Because the Braeburn study was focused on opioid users who experienced moderate to severe chronic pain, one important aspect of the study was study subjects' own subjective perception about how the CAM 2038 buprenorphine injection managed their chronic pain, and how they felt on a daily basis. Therefore, as part of the protocol, study subjects were required to complete a daily diary documenting their subjective pain experience, the time of the day, and the need for any rescue medication. Because the vast majority of the study subjects were not experiencing chronic pain, were not users of prescription opioids, and/or were not actually participating in the study, and therefore none of the subjects completed subject diaries, at SAMI ANWAR's direction, MID

COLUMBIA RESEARCH employees falsified these subject diaries, which were required to be completed by the study subjects themselves, in anticipation of the October Audit. At SAMI ANWAR's direction, virtually all MID COLUMBIA RESEARCH employees participated in the falsification of subject diaries, so that different subject diaries would contain different-looking handwriting, and it would appear to the auditors that the subjects had completed the diaries themselves. Because there were more purported study subjects who were not actually participating in the study than available MID COLUMBIA RESEARCH employees, SAMI ANWAR directed that the MID COLUMBIA RESEARCH employees hold their pens differently for different purported subjects, so that the handwriting would not look identical and it would appear that the subjects had completed the diaries themselves. At SAMI ANWAR's direction, MID COLUMBIA RESEARCH employees not only falsified the subject diaries, but completed them with information calculated to show the study subjects' pain levels were decreasing, so it would appear as though the study was progressing as intended and the study subject would appear to continue to be eligible so that MID COLUMBIA RESEARCH could continue billing Braeburn and Medpace for that subject.

85. Defendants' efforts to falsify subject diaries were ultimately unsuccessful, in part, because, unknown to Defendants, Medpace had obtained a number of subject diaries during their September 2017 monitoring visit. Accordingly, when Defendants presented the newly falsified diaries to the Medpace and Braeburn auditors during the October Audit, the auditors were able to compare the two sets of diaries for the same subjects, and document that Defendants had altered the diaries to make it appear as though the subjects were still eligible for the study. The October Audit specifically documented that subject diaries for Subject 068-012, Subject 068-013, Subject 068-014, Subject 068-015,

and Subject 068-018 that had been obtained during the September monitoring visit did not support continued eligibility, and that by the time of the October Audit, MID COLUMBIA RESEARCH had replaced those subject diaries with new falsified subject diaries containing falsified data that did support subject eligibility. Ultimately, the auditors considered this finding critical and recommended that all data from MID COLUMBIA RESEARCH be thrown out and that MID COLUMBIA RESEARCH's participation be terminated, which Braeburn and Medpace did on October 23, 2017.

Defendants' Conspiracy Extended to a Proposed Study Involving GHB

86. The Conspiracy was not restricted to the Braeburn Study, but included other studies. For example, on May 12, 2017, SAMI ANWAR submitted an application to the DEA to conduct research using GHB as a study drug in a proposed study regarding patients with narcolepsy, which is a sleep disorder. SAMI ANWAR's application falsely represented that Dr. Doe would also be the clinical investigator on this study.

87. As with the Braeburn Study, Dr. Doe was never intended to personally conduct or supervise any study involving GHB. In fact, he was unaware that the study even existed at the time of the application's submittal, and only learned of it much later when shown the application by DEA investigators. SAMI ANWAR forged Dr. Doe's signature on the application to the DEA and on documents submitted in support of the application, including a falsified curriculum vitae on which SAMI ANWAR forged Dr. Doe's signature and which contained false information.

88. SAMI ANWAR's application for the GHB Study was not been approved because neither DEA nor Flamel, nor INC Research were ever able to get in touch with Dr. Doe, despite repeated efforts. In September 2017, after Dr. Doe

first became aware that SAMI ANWAR used his name and forged his signature on the GHB Study application, Dr. Doe withdrew the application.

COUNT 2
CONSPIRACY TO COMMIT MAIL FRAUD

89. The Grand Jury re-alleges and incorporates by reference paragraphs 1 through 88 of the Indictment as if fully set forth herein. Further, the allegations in all other counts in the Indictment are re-alleged and incorporated into this count as if fully set forth herein.

90. Beginning on a date unknown to the Grand Jury, but no later than on or about July 20, 2016, and continuing until at least on or about January 24, 2018, in the Eastern District of Washington, the Defendants SAMI ANWAR, MID COLUMBIA RESEARCH, ZAIN RESEARCH, and persons both known and unknown to the Grand Jury, did knowingly combine, conspire, and agree to commit certain offenses against the United States including the following offenses, to wit, knowingly devised and intended to devise a scheme and artifice to defraud Braeburn, Medpace, CSM, other sponsors and CROs, and prospective sponsors and CROs, both known and unknown to the Grand Jury, and to obtain payments from Braeburn, Medpace, and other sponsors and prospective sponsors, both known and unknown to the Grand Jury, and hydrocodone and morphine from CSM, using interstate mails, the United States Postal Service, and private and commercial interstate carriers in order to execute and attempt to execute the said scheme and artifice to defraud in the ways, manners, and means described in paragraphs 35 through 88 of this Indictment and referred to herein as the Conspiracy, in violation of 18 U.S.C. §§ 1341, 1349.

91. As part of the Conspiracy the checks sent by Medpace, and funded by Braeburn, to MID COLUMBIA RESEARCH attention SAMI ANWAR, were sent

using the interstate mails via the United States Postal Service and Federal Express, a private interstate commercial carrier. In addition, the drug shipments of hydrocodone and morphine from CSM received by MID COLUMBIA RESEARCH as part of the Conspiracy, were sent in the interstate mails via United Parcel Service (UPS) a private interstate commercial carrier.

COUNTS 3 - 25
WIRE FRAUD

92. The Grand Jury re-alleges and incorporates by reference paragraphs 1 through 91 of the Indictment as if fully set forth herein. Further, the allegations in all other counts in the Indictment are re-alleged and incorporated into this count as if fully set forth herein.

93. On or about each of the dates set forth below, in the Eastern District of Washington, the Defendants SAMI ANWAR, MID COLUMBIA RESEARCH, and ZAIN RESEARCH, and persons both known and unknown to the Grand Jury, for the purpose of executing the Conspiracy described above and to obtain money from Braeburn and Medpace, and attempting to do so, did knowingly and with intent to defraud, based on materially false and fraudulent representations, omissions, pretenses, and promises, transmit and cause to be transmitted by means of wire communication in interstate commerce the signals and sounds described below for each count, each transmission constituting a separate count:

Count	Date of Wire	Description of Wire
3	On or about December 9, 2016	Email from an employee of SAMI ANWAR with initials H.E. to a Medpace Clinical Research Associate with initials M.K., with subject line "RE: Braeburn HS-16-555/ PI Contact Number, providing SAMI ANWAR's cellular telephone number and falsely stating

		that the number was for Dr. Doe's cellular telephone, and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
4	On or about July 19, 2017	IRT entry, transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio, for Subject 068-014 for Site 068 of the Braeburn Study falsely representing that one syringe of CAM 2038 was dispensed to that subject on July 19, 2017.
5	On or about July 26, 2017	EDC entry for Subject 068-014 in Braeburn Study HS-16-555 on Form (EGYN) Any ECG Test Results, with a false entry of "YES" for "Was a 12-lead ECG performed?" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
6	On or about July 26, 2017	EDC entry for Subject 068-014 in Braeburn Study HS-16-555 on Form (PEYN_ISE) Any Injection Site Exam, with a false entry of "YES" for "Was Injection Site Exam Performed?" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
7	On or about July 28, 2017	EDC entry for Subject 068-030 in Braeburn Study HS-16-555 on Form (IEYN) Any Inclusion Criteria Not Met, with a false entry of

		"YES" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
8	On or about August 14, 2017	IRT entry, transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio, for Subject 068-027 for Site 068 of the Braeburn Study falsely representing that one syringe of CAM 2038 was dispensed to that subject on August 14, 2017.
9	On or about August 15, 2017	IRT entry, transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio, for Subject 068-024 for Site 068 of the Braeburn Study falsely representing that 42 tablets of Hydrocodone were dispensed to that subject on August 15, 2017.
10	On or about August 15, 2017	IRT entry, transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio, for Subject 068-022 for Site 068 of the Braeburn Study falsely representing that one syringe of CAM 2038 was dispensed to that subject on August 15, 2017
11	On or about August 22, 2017	EDC entry for Subject 068-022 in Braeburn Study HS-16-555 on Form (IEYN) Any Inclusion Criteria Not Met, with a false entry of "YES" for "Did the subject meet all eligibility criteria?" and transmitted via interstate wires

		from Richland, Washington to Cincinnati, Ohio.
12	On or about August 22, 2017	EDC entry for Subject 068-024 in Braeburn Study HS-16-555 on Form (IEYN) Any Inclusion Criteria Not Met, with a false entry of "YES" for "Did the subject meet all eligibility criteria?" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
13	On or about August 24, 2017	EDC entry for Subject 068-027 in Braeburn Study HS-16-555 on Form (IEYN) Any Inclusion Criteria Not Met, with a false entry of "YES" for "Did the subject meet all eligibility criteria?" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
14	On or about August 29, 2017	EDC entry for Subject 068-014 in Braeburn Study HS-16-555 on Form (Injection Site Exam) CURRENT INJECTION SITE, A, with a false entry of the date of injection as "14/Aug/2017," a false entry of the injection site type as "CURRENT INJECTION SITE," a false entry of the location of the injection as "A," and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.

15	On or about August 29, 2017	EDC entry for Subject 068-027 in Braeburn Study HS-16-555 on Form (LB_CNTRL) Laboratory Test Reults- Central Processing, with a false entry of "YES" for "Was the blood sample collected?" a false entry of "YES" for "Was the urine sample collected?" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
16	On or about August 30, 2017	IRT entry, transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio, for Subject 068-028 for Site 068 of the Braeburn Study falsely representing that 28 tablets of Hydrocodone were dispensed to that subject on August 30, 2017.
17	On or about September 1, 2017	EDC entry for Subject 068-022 in Braeburn Study HS-16-555 on Form (Injection Site Exam) CURRENT INJECTION SITE, A, with a false entry of the date of injection as "15/Aug/2017," a false entry of the injection site type as "CURRENT INJECTION SITE," a false entry of the location of the injection as "A," and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
18	On or about September 1, 2017	EDC entry for Subject 068-028 in Braeburn Study HS-16-555 on Form (DA) Drug Accountability, with a false entry of "YES," for

		"Was study Rescue Medication Dispensed?" a false entry of the date dispensed as "30/Aug/2017," a false entry of "28" for "What is the amount dispensed? (in tablets)," and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
19	On or about September 5, 2017	EDC entry for Subject 068-024 in Braeburn Study HS-16-555 on Form (DA) Drug Accountability, with a false entry of "YES," for "Was study Rescue Medication Dispensed?" a false entry of the date dispensed as "15/Aug/2017," a false entry of "42" for "What is the amount dispensed? (in tablets)," and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
20	On or about September 13, 2017	IRT entry, transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio, for Subject 068-028 for Site 068 of the Braeburn Study falsely representing that 14 tablets of Hydrocodone were dispensed to that subject on September 13, 2017.
21	On or about September 14, 2017	EDC entry for Subject 068-028 in Braeburn Study HS-16-555 on Form (DA) Drug Accountability, with a false entry of "YES," for "Was study Rescue Medication Dispensed?" a false entry of the date dispensed as

		"13/Sep/2017," a false entry of "14" for "What is the amount dispensed? (in tablets)," and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
22	On or about October 3, 2017	IRT entry, transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio, for Subject 068-024 for Site 068 of the Braeburn Study falsely representing that 14 tablets of Hydrocodone were dispensed to that subject on October 3, 2017.
23	On or about October 4, 2017	EDC entry for Subject 068-024 in Braeburn Study HS-16-555 on Form (DA) Drug Accountability, with a false entry of "YES," for "Was study Rescue Medication Dispensed?" a false entry of the date dispensed as "03/Oct/2017," a false entry of "14" for "What is the amount dispensed? (in tablets)," and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
24	On or about October 9, 2017	EDC entry for Subject 068-014 in Braeburn Study HS-16-555 on Form (Date of Visit) 9/22/2017, with a false entry of "YES" for "Did the subject attend this visit?" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.

25	On or about October 9, 2017	EDC entry for Subject 068-014 in Braeburn Study HS-16-555 on Form (VSYN_DOSE) Any Vital Signs-Pre/Post Test Dose, with a false entry of "YES" for "Were vital signs taken?" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.

All in violation of 18 U.S.C. § 1343.

COUNTS 26 - 40
MAIL FRAUD

94. The Grand Jury re-alleges and incorporates by reference paragraphs 1 through 93 of the Indictment as if fully set forth herein. Further, the allegations in all other counts in the Indictment are re-alleged and incorporated into this count as if fully set forth herein.

95. On or about each of the dates set forth below, in the Eastern District of Washington, the DEFENDANTS SAMI ANWAR, MID COLUMBIA RESEARCH, and ZAIN RESEARCH, and persons both known and unknown to the Grand Jury, for the purpose of executing the Conspiracy described above, and to obtain money from Braeburn and Medpace, and to obtain property, in the form of hydrocodone and morphine from CSM, and attempting to do so, did knowingly and with intent to defraud, cause to be delivered by the means specified below, the below mailings, each mailing constituting a separate count:

Count	Date of Mailing	Description of Mailing
26	On or about March 17, 2017	Check 68676, totaling $3,582.00, made out to "Mid Columbia Research, LLC"

		for Braeburn Study payment through January 2017, sent in the interstate mails via the United States Postal Service.
27	On or about April 13, 2017	Check 69161, totaling $9,639.00, made out to "Mid Columbia Research, LLC" for Braeburn Study payment through February 2017, sent in the interstate mails via the United States Postal Service.
28	On or about May 25, 2017	Check 69821, totaling $17,192.00, made out to "Mid Columbia Research, LLC" for Braeburn Study payment through March 2017, sent in the interstate mails via the United States Postal Service.
29	On or about June 8, 2017	Check 70067, totaling $21,666.00 made out to "Mid Columbia Research, LLC" for Braeburn Study payment through April 2017, sent in the interstate mails via the United States Postal Service.
30	On or about July 6, 2017	Check 70563, totaling $16,690.50 made out to "Mid Columbia Research, LLC" for Braeburn Study payment through May 2017, sent in the interstate mails via the United States Postal Service.
31	On or about August 14, 2017	Check 71010, totaling $36,702.00 made out to "Mid Columbia Research, LLC"

		for Braeburn Study payment through June 2017, sent in the interstate mails via the United States Postal Service.
32	On or about September 7, 2017	Check 71628, totaling $40,000.50, made out to "Mid Columbia Research, LLC" for Braeburn Study payment through July 2017, sent in the interstate mails via the United States Postal Service.
33	On or about October 13, 2017	Check 72068, totaling $66,691.50, made out to "Mid Columbia Research, LLC" for Braeburn Study payment through August 2017, sent in the interstate mails via the United States Postal Service.
34	On or about November 27, 2017	Check 72873, totaling $58,479.30, made out to "Mid Columbia Research, LLC" for Braeburn Study payment through September 2017, sent in the interstate mails via Federal Express, a private interstate commercial carrier.
35	On or about November 22, 2016	CSM Shipment Order number 60372-112216 containing hydrocodone and morphine rescue medication, in response to the DEA Form-222 submitted on or about November 15, 2016, sent in the interstate mails via United Parcel

		Service (UPS), a private interstate commercial carrier.
36	On or about June 1, 2017	CSM Shipment Order number 68268-053117 containing hydrocodone and morphine rescue medication, in response to the DEA Form-222 submitted on or about May 31, 2017, sent in the interstate mails via UPS, a private interstate commercial carrier.
37	On or about July 24, 2017	CSM Shipment Order number 70550-072117 containing hydrocodone and morphine rescue medication, in response to the DEA Form-222 submitted on or about July 19, 2017, sent in the interstate mails via UPS, a private interstate commercial carrier.
38	On or about August 23, 2017	CSM Shipment Order number 71738-082317 containing hydrocodone and morphine rescue medication, in response to the DEA Form-222 submitted on or about August 22, 2017, sent in the interstate mails via UPS, a private interstate commercial carrier.
39	On or about September 26, 2017	CSM Shipment Order number 72994-092617 containing hydrocodone and morphine rescue medication, in response

		to the DEA Form-222 submitted on or about September 11, 2017, sent in the interstate mails via UPS, a private interstate commercial carrier.
40	On or about September 28, 2017	CSM Shipment Order number 73085-092717 containing hydrocodone and morphine rescue medication, in response to the DEA Form-222 submitted on or about September 25, 2017, sent in the interstate mails via UPS, a private interstate commercial carrier.

All in violation of 18 U.S.C. § 1341.

COUNTS 41 - 46
FRAUDULENTLY OBTAINING CONTROLLED SUBSTANCES

96. The Grand Jury re-alleges and incorporates by reference paragraphs 1 through 95 of the Indictment as if fully set forth herein. Further, the allegations in all other counts in the Indictment are re-alleged and incorporated into this count as if fully set forth herein.

97. On or about the dates below, in the Eastern District of Washington, the DEFENDANTS SAMI ANWAR, MID COLUMBIA RESEARCH, and ZAIN RESEARCH, and persons both known and unknown to the Grand Jury, knowingly and intentionally obtained and acquired morphine and hydrocodone, both Schedule II controlled substances, by misrepresentation, fraud, forgery, deception, and subterfuge, to wit, the Conspiracy, including, but not limited to, by submitting and causing to be submitted forged and fraudulent DEA-222 forms, purportedly signed

by Dr. Doe and affixing Dr. Doe's DEA Registration Number, all without his knowledge or authorization, and through MID COLUMBIA RESEARCH to Clinical Supplies Management Inc., (CSM) of Fargo, North Dakota, fraudulently ordering and obtaining amounts and quantities of the Schedule II controlled substances listed below, each instance constituting a separate count:

Count	Order Date	Date Obtained	Controlled Substances Obtained
41	On or about November 15, 2016	On or about November 23, 2016	15 packages of 100 count bottles of hydrocodone/acetaminophen 5 mg/325 mg tablets with lot or serial numbers HD16216_0697 to HD16216_0711 3 packages of 100 count bottles of morphine sulfate 15 mg tablets with lot or serial numbers 659418C_141 to 659418C_143
42	On or about May 31, 2017	On or about June 2, 2017	15 packages of 100 count bottles of hydrocodone/acetaminophen 5 mg/325 mg tablets with lot or serial numbers HD16216_1245 to HD16216_1259 1 package of 100 count bottle of morphine sulfate 15 mg tablets with lot or serial number 659418C_236

43	On or about July 19, 2017	On or about July 25, 2017	11 packages of 100 count bottles of hydrocodone/acetaminophen 5 mg/325 mg tablets with lot or serial numbers HD16216_1531 to HD16216_1541 1 package of 100 count bottle of morphine sulfate 15 mg tablets with lot or serial number 659418C_274
44	On or about August 22, 2017	On or about August 24, 2017	11 packages of 100 count bottles of hydrocodone/acetaminophen 5 mg/325 mg tablets with lot or serial numbers HD16216_1694 to HD16216_1704 1 package of 100 count bottle of morphine sulfate 15 mg tablets with lot or serial number 659418C_292
45	On or about September 11, 2017	On or about September 27, 2017	11 packages of 100 count bottles of hydrocodone/acetaminophen 5 mg/325 mg tablets with lot or serial numbers HD16216_1826 to HD16216_1836
46	On or about September 25, 2017	On or about September 29, 2017	4 packages of 100 count bottles of hydrocodone/acetaminophen 5 mg/325 mg tablets with lot or

			serial numbers HD16216_1894 to HD16216_1897 1 package of 100 count bottle of morphine sulfate 15 mg tablets with lot or serial number 764031A_410

All in violation of 21 U.S.C. § 843(a)(3).

COUNT 47
FURNINSHING FALSE OR FRAUDULENT MATERIAL INFORMATION

98. The Grand Jury re-alleges and incorporates by reference paragraphs 1 through 97 of the Indictment as if fully set forth herein. Further, the allegations in all other counts in the Indictment are re-alleged and incorporated into this count as if fully set forth herein.

99. On or about May 12, 2017, in the Eastern District of Washington, the Defendants SAMI ANWAR, MID COLUMBIA RESEARCH, and ZAIN RESEARCH, and persons both known and unknown to the Grand Jury, knowingly and intentionally furnished false and fraudulent material information in a DEA Form 225, an application for registration under the Controlled Substances Act required to be made, kept, and filed under 21 U.S.C. § 823(b) and 21 CFR § 1301, to wit: forging Dr. Doe's signature and affixing Dr. Doe's DEA Registration Number, all without his knowledge or authorization, and supplying other false and fraudulent information in Defendants' application to the DEA for the GHB Study, in order to obtain authorization to possess and distribute GHB, a Schedule I controlled substance. All in violation of 21 U.S.C. § 843(a)(4)(A).

NOTICE OF FORFEITURE ALLEGATIONS

The allegations contained in this Indictment are hereby re-alleged and incorporated herein by this reference for the purpose of alleging forfeiture.

Pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c), upon conviction of an offense(s) in violation of 18 U.S.C. §§ 1343, 1349, Wire Fraud; and/or 18 U.S.C. §§ 1341, 1349, Mail Fraud, as alleged in this Indictment, the Defendants, SAMI ANWAR, MID COLUMBIA RESEARCH, LLC, and ZAIN RESEARCH, LLC, shall forfeit to the United States of America any property, real or personal, which constitutes or is derived from proceeds traceable to the offense(s). The property sought for forfeiture includes, but is not limited to, the following:

Money Judgment

A sum of money of at least $274,642.80 in United States currency, representing the amount of proceeds obtained from the wire fraud and/or mail fraud violations.

If any of the property described above, as the result of any act or omission of Defendants:

(a) cannot be located upon the exercise of due diligence;

(b) has been transferred or sold to, or deposited with, a third party;

(c) has been placed beyond the jurisdiction of the court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty,

the United States shall be entitled to forfeiture of substitute property pursuant to

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21 U.S.C. § 853(p), as incorporated by 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c).

DATED this 6 day of November, 2018.

A TRUE BILL

Joseph H. Harrington
United States Attorney

Daniel Hugo Fruchter
Assistant United States Attorney

Tyler H.L. Tornabene
Assistant United States Attorney